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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/933,989	08/20/2001	Shoji Uchiyama	47061/JWP/A596	7693

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OMORI & YAGUCHI USA, LLC
EIGHT PENN CENTER, SUITE 1360
1628 JOHN F. KENNEDY BOULEVARD
PHILADELPHIA, PA 19103

EXAMINER	
KIM, JENNIFER M	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/933,989	UCHIYAMA ET AL.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-69* is/are pending in the application.

4a) Of the above claim(s) *1-30,46-48 and 62-64, 68, 69* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-45,49-61,65-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *15* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's election of species with traverse of a single autoimmune disorder as rheumatoid arthritis is acknowledged. The traversal is on the ground(s) that all of the clamed disorders at issue are autoimmune diseases are often collectively grouped under the general umbrella of "autoimmune diseases" and a search of these disorders would not pose a serious burden of the Examiner and that according to MPEP 803, there must be two criteria for patentably distinct inventions including a serious burden. This is not found persuasive because the claims are drawn to various unrelated disorders since each of the medical disorders have different known etiology and different treatment involving unrelated pharmaceutical compounds (e.g. diabetes is completely different than thyroid goiter). Therefore the requirement of species election set forth in last Office Action is deemed proper and made final.

The elected Group II, claims 31-45, 49-61 and 65-67 have been examined only to the extent of Applicants' elected specie of treating rheumatoid arthritis.
Claims 1-30, 46-48, 62-64, 68 and 69 are withdrawn from consideration since they are non-elected invention.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 31-45, 49-61 and 65-67 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the "treatment of rheumatoid arthritis", does not reasonably provide enablement for the "prevention of rheumatoid arthritis". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

3. Enablement is considered in view of the Wands factors (MPEP 2164.01(a)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, predictability of the prior art, state of the prior art and the amount of experimentation necessary. All of the **Wands factors** have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the Invention: All of the rejected claims are drawn to a method of preventing and treating rheumatoid arthritis in a subject with an effective amount of composition comprising *Agaricus blazei Murill*. The nature of the invention is extremely complex in that it encompasses the actual prevention of an autoimmune disorder (i.e. rheumatoid arthritis) such that the subject treated with above composition does not contract rheumatoid arthritis.

Breath of the Claims: The complex of nature of the claims greatly exacerbated by breath of the claims. The claims encompass prevention of a complex rheumatoid arthritis in a subject which may be initiated by multiple factors involving immunologic changes (i.e. involves many different immunogolbulins and materials (collagenase, interleukin-1, and prostaglandins) or combination of immunoglobulins and the materials). Each of which may or may not be addressed by the administration of the claimed composition comprising *Agaricus blazei Murill.*

Guidance of the Specification: The guidance given by the specification as to how one would administered the claimed composition comprising *Agaricus blazei Murill* to a subject in order to actually **prevent** rheumatoid arthritis is minimal. All of the guidance provided by the specification is directed towards treatment rather than **prevention** of rheumatoid arthritis.

Working Examples: All of the working examples provided by the specification are directed toward the treatment rather than **prevention** of rheumatoid arthritis.

State of the Art: While the state of the art is relatively high with regard to treatment of autoimmune disorders(i.e. rheumatoid arthritis), the state of the art with regard to **prevention** of such disorders is underdeveloped. In particular, there do not appear to be any examples or teachings in the prior art wherein a compound similar to the claimed composition comprising *Agaricus blazei Murill* was administered to a subject to **prevent** development of rheumatoid arthritis.

Predictability of the Art: The lack of significant guidance from the specification or prior art with regard to the actual **prevention** of rheumatoid arthritis in a human subject with the claimed composition makes practicing the claimed invention unpredictable in terms of prevention of rheumatoid arthritis.

The amount of Experimentation Necessary: In order to practice claimed invention of preventing rheumatoid arthritis, one of skilled in the art would have to first envision a combination of appropriate pharmaceutical carrier, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system for one of the claimed compounds and test the combination in the model system to determine whether or not the combination is effective for the **prevention** of rheumatoid arthritis. If unsuccessful, which is likely given the lack of significant guidance from the specification or prior art regard prevention of rheumatoid arthritis with any compound, one of skill in the art would have to then either envision a modification of the first combination of pharmaceutical compound, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system, or envision an entirely new combination of the above, and test the system again. If again unsuccessful, which is likely given the lack of significant guidance form the specification of prior art regarding **prevention** of rheumatoid arthritis with any compound, the entire, unpredictable process would have to be repeated until successful. Therefore, it would require undue, unpredictable experimentation to practice the claimed invention to

prevent the development of rheumatoid arthritis in a subject by administration of claimed composition.

Therefore, a method of **preventing** and treating a subject rheumatoid arthritis administering composition comprising *Agaricus blazei Murill* is not considered to be enabled by the instant specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 31-45, 49-61 and 65-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Itokawa (US Patent Application Publication US 2002/0110564A1) in view of Fujimiya et al. (U.S.Patent No. 6,093,694) of record.

Itokawa discloses nutriceutical composition prepared from the Agaricus blazei Murill contains antioxidants which reduce the level of free radicals in the body and these free radicals implicated in rheumatoid arthritis. (abstract, column 1, paragraph [0010]).

Itokawa does not teach the process of obtaining Agaricus blazei Murill extract and the effective amount set forth in claims 50-54, duration of therapy set forth in claims 57, 58, 65 and 66.

Fujimiya et al. teach the process of obtaining Agaricus blazei Murill extract set forth in claims 31 and 41. (abstract). Fujimiya et al. teach that substance (polysaccharide mainly composed of 1-4 α-glucan and 1-6-β- glucan) obtained by the process can be administered orally (tablets, capsules, granules) or parentally (injection). (column 5, lines 1-10, lines 20-48).

It would have been obvious to one of ordinary skill in the art to employ Agaricus blazei Murill extract (e.g. polysaccharide mainly composed of 1-4 α-glucan and 1-6-β-glucan) obtained by Fujimiya et al's process because Agaricus blazei Murill contains antioxidants which reduce the level of free radicals in the body which implicate rheumatoid arthritis as taught by Itokawa and the process of obtaining Agaricus blazei Murill extract set forth in claims 31 and 41 are well-known by Fujimiya et al.

One would have been motivated to make such modification in order to successfully treating rheumatoid arthritis patients with known antioxidant benefit.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 703-308-2232. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 703-305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

Jmk
January 16, 2004

1/26/04